4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2226]

Cheese Products Deviating from Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the extension of a temporary permit issued to Bongards Creameries (the applicant) to market test several pasteurized standardized cheeses that deviate from the U.S. standards of identity for cheese products. The extension allows the applicant to continue to evaluate commercial viability of the products and to collect data on consumer acceptance of the products, in support of a petition to amend the standard of identity for cheese products. We also invite other interested parties to participate in the market test.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity of cheese products that may result from the petition or 30 days after denial of the petition.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), we issued a temporary permit to Bongards Creameries, 250 Lake Drive East, Chanhassen, MN 55317, to market test products that deviate from the standards of identity for cheese products under §§ 133.167, 133.169, 133.170, and 133.173 (21 CFR 133.167, 133.169, 133.170, and 133.173) (85 FR 80118, December 11, 2020). We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for cheese products

issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate marketing tests of cheese products.

The test products deviate from the standards of identity for cheese products under §§ 133.167, 133.169, 133.170, and 133.173. For the purpose of this permit, natamycin, which is not permitted under the standards of identity for these cheese products, would be added as a mold inhibitor in the standardized cheeses. The inhibitor would be incorporated into blended and processed cheese just prior to pasteurization and further cast into slices (or packaging into loaves or other final forms as in the case of pasteurized process cheese spread). Natamycin, which is stable under typical thermal processing conditions for pasteurized cheeses, would be added directly to cheese blends just prior to pasteurization, as is done with other mold inhibitors such as sorbic acid, sodium propionate, and their approved variants. The final concentration of natamycin would not exceed 20 parts per million and would be effective at producing process and blended slices with a shelf life of up to 150 days before seeing mold growth.

The test products meet all the requirements of the standard with the exception of this deviation.

On December 22, 2022, the applicant asked us to extend the temporary permit so the applicant could have more time to market test the cheese products and gain additional consumer acceptance in support of the petition to amend the standard for cheese products. We find that it is in the interest of consumers to extend the permit for continued market testing of the cheese products to gain additional information on consumer expectations and acceptance. Therefore, under § 130.17(i), we are extending the temporary permit granted to Bongards Creameries for temporary marketing of a maximum of 100 million pounds (45,359,237 kilograms) of cheese products to provide continued market testing of the specified amount of product for the applicant on an annual basis. The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for cheese products that may result from the petition

or 30 days after denial of the petition. All other conditions and terms of this permit remain the same.

In addition, we invite interested persons to participate in the market test under the conditions of the permit, except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Branch Chief, Product Evaluation Labeling Branch, Division of Food Labeling and Standards, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, via FDAFoodsProgramTMP@fda.hhs.gov. The notification must describe the test products and the area of distribution, specify and justify the amount requested, and include the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested) (see § 130.17(c)). The information panels on the labels of the test products must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by 21 CFR part 101.

Dated: May 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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